

TEXAS CENTER FOR JOINT REPLACEMENT

Roger H. Emerson, Jr., M.D. Board Certified Orthopaedic Surgeon

John M. Hillyard, M.D.
Board Certified Orthopaedic Surgeon

William C. Head, M.D.

Board Certified Orthopaedic Surgeon

4846 99 BE330 00 50

December 20, 1999

Document Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE: Docket No. 97N-484S

TO WHOM IT MAY CONCERN:

These comments are in reference to the use of bone allograft. As an orthopaedic clinician, I have used allograft bone since the late 1970s. There is documentation in the peer review literature documenting the safety of these grafts.

I am satisfied with the current bone banking regulations. This graft material is an integral part of day to day orthopaedic surgery. With a 20+ year history, I think the track record speaks for itself.

Sincerely,

Roger H. Emerson, Jr., M.D.

My When

RHEjr/bkl

97N 484S

0352



6300 W. Parker Road Suite 220 Plano, Texas 75093-7916



Document Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 ROCKVIlle, MD 20852, 20857/0003